Chapter 4: Estimation of Average and Upper-End Risk

4.1 Introduction

Exposure assessments evaluate scenarios that are a combination of facts, data, assumptions, inferences, and professional judgments about environmental settings, contaminant characterization exposure pathways, population characterization, and contaminant intake rates. The contaminant concentration, the intake rate, and the duration of exposure are the primary variables in quantitative exposure assessments. The general exposure intake equation is delineated as follows:

$$\text{Exposure Intake} = \frac{C \times IR \times EF \times ED}{BW \times AT}$$

where:

C = Contaminant Concentration

IR = Intake/Contact Rate

EF = Exposure Frequency

ED = Exposure Duration

BW = Body Weight

AT = Averaging Time

Human health risk assessments conducted under the EPA Superfund program have historically made conservative exposure assumptions when assigning numerical values to these key variables in order to be protective of public health (CEQ, 1985; USEPA, 1986a). The calculation of conservative estimates of risk reflects the complexities of natural systems and the limitations of science in characterizing risk. The evolution of CERCLA public health risk assessments has been driven by the recognition that uncertainties are inherent in the estimation of human health risks and by the incremental gain of knowledge and experience on how exposure assumptions affect the timely completion of the CERCLA process.

EPA recognized that there needed to be a full characterization of risk for risk assessments to be perceived as a reliable tool for informative decisionmaking, and thus heighten their credibility. This meant that assessors would need to associate numerical estimates with a discussion of the level of confidence in the exposure estimates for key exposure pathways and related assumptions (USEPA, 1992a). Over the years CERCLA guidance began to use the following loosely defined terms to describe risks and exposure scenarios

- reasonable maximum exposure (RME),

- reasonable worst case,
- worst case, and
- maximum exposed individual (MEI)

This section provides an overview of the use and evolution of these terms and the associated statutes and regulations from which they derived.

4.2 Discussion of Estimation of Average and Upper-End Risk in Statutes, Regulations, and Guidelines

4.2.1 Statutes and Regulations

CERCLA, SARA, and the 1985 NCP (USEPA, 1985a) did not define or discuss any of the above terms. The 1990 revisions to the NCP (USEPA, 1990) directed that Superfund cleanup decisions be based on RME estimates, which are based on "likely scenarios for those individuals near a site that would receive the greatest exposure. " According to the 1990 NCP, the goal of the RME concept is to combine upper-bound and mid-range exposure factors so that the resulting exposure scenario is "protective and reasonable, not the worst possible case." The NCP did not discuss which values should be average or 95th percentile, or how to mix them.

4.2.2 Initial CERCLA Exposure Assessment Guideline Conceptual Framework

As mentioned previously, guidance on how to conduct CERCLA risk assessments was initially provided in the Superfund Public Health Evaluation Manual (SPHEM) (USEPA, 1986a) and the Superfund Exposure Assessment Manual (SEAM) (USEPA, 1988a). These two supporting documents provided the initial exposure assessment conceptual framework for CERCLA activities.

Superfund Public Health Evaluation Manual (SPHEM)

SPHEM provides detailed guidance on how to conduct a public health evaluation at a Superfund site. Exposure assessment is defined as an estimation of the probable dose of a substance to a target population. Because the actual dose received by actual people is generally uncertain, the exposure assessment requires the use of complex exposure models that are based on incomplete knowledge of how hazardous substances are transported and undergo transformation in the environment and how they affect human health. SPHEM indicates that the most appropriate models for Superfund sites are "simple environmental fate models using conservative (i.e., reasonable worst case) assumptions. " No definition is given to what is meant by "reasonable worst case."

SPHEM states that "the Superfund risk assessment process is based on concern' for both individual risk and risk to exposed populations" and recommends that "an exposure point that should be evaluated for an exposure pathway is the geographic point of highest individual exposure." While SPHEM does not define or specifically show how to estimate a "highest individual exposure," it recognizes the following approaches during the calculation of exposure points:

- one approach would calculate a single conservative measure of risk ("use a conservative, not necessarily worst-case, approach in making the assumptions");

- another approach would require two measures of risk described as "best estimates and conservative upper bound estimates"; and yet,

- another approach, "more complex and time consuming than a deterministic approach" would be to "model the important variables determining chemical concentration and risk stochastically" and provide an "estimation of a risk distribution, from which median and 90th percentile (or other upperbound) values can be determined."

Exposure assessments performed under SPHEM were directed toward using the second approach (i.e., estimating a range of exposure scenarios a "best estimate" and an "upper-bound" scenario). The best estimate was quantified using the average concentration of the detected contaminant concentrations and conservative default values and exposure assumptions. The upper-bound estimate was quantified using the maximum detected contaminant level in a specific medium at a site and the most conservative default values and exposure assumptions related to a hypothetical highest individual exposure. According to SPHEM, this approach would provide "not only an estimate of the risk magnitude but also a good indication of the overall uncertainty of the analysis" (USEPA, 1986a).

Superfund Exposure Assessment Manual (SEAM)

SEAM provided guidance for assessing contaminant release, environmental fate and transport, and human exposure to contaminants emanating from hazardous waste sites. SEAM was developed to support consistency in conducting exposure assessments at Superfund sites. It compiled and integrated various methodological approaches published by EPA and others.

SEAM recognizes that the approach to conducting exposure assessments is conservative: "While it is traditional in exposure assessments to make conservative assumptions in the absence of data, such assumptions must be reasonable." However, it warns of the possibility that multiple conservative assumptions may result in extreme and unrealistic assessment "Use of reasonably conservative assumptions at each step may produce cumulative assessment results that are overly conservative and thus unreasonable."

On communicating the uncertainty associated with the estimated level of risk, SEAM recommends including a standard deviation or the 95% confidence limit. As indicated in the earlier Guidelines for Estimating Exposures, SEAM also suggested that further research was needed on the use of a distributional approach to characterize exposure uncertainty.

Both SPHEM and SEAM employ terms such as "reasonable" and "best estimate," but they do not practically define those terms other than suggesting the use of professional judgement in choosing the various exposure variables and in warning of cumulative effects of using conservative values. Although SPHEM and SEAM were published with the intention of performing more consistent Superfund risk assessments, the use of undefined subjective terms created contradictory interpretations among risk assessment personnel and across EPA programs and regions. For example, responding to public comments expressing concerns that worst-case estimates would be used when data are limited or absent, the EPA stated in Guidelines for Estimating Exposures (USEPA, 1986b) that "The Guidelines do not encourage the use of worst-case assessments, but rather the development of realistic assessments based on the best data available. However, the Agency will err on the side of public health when evaluating uncertainties when data are limited or nonexistent. "

The 16th Annual Report of the Council on Environmental Quality (CEQ, 1985) described EPA's overall strategy as "inefficient and unable to solve environmental problems." The report argues that the cause originates in part in the "uncertainty of the scientific basis for action. " The CEQ also observes that policymaking at EPA was dominated by cancer control "not only because it is dreaded and widespread, but because a peculiarity of risk assessment, the inability to set a threshold dosage for carcinogens, insures that when some exposure is found, some risk can be calculated."

4.2.3 Overcoming Initial Guidance Conceptual Framework Limitations

SARA promulgated amendments to CERCLA'S hazard ranking system in effect since September of 1984 to "assure, to the maximum extent feasible, that the system accurately assesses the relative degree of risk to human health. " SARA's push for more accurate human health risk assessments is reflected in the establishment of various EPA programs, in the revision of the RI and FS program, and in the publication of Risk Assessment Guidance for Superfund, Volume I (RAGS) (USEPA, 1989a) and the Exposure Factors Handbook (EFH) (USEPA, 1989b).

In 1988, the RI/FS document, which reflected amendments made to CERCLA in 1986, stated the following about exposure assessments:

> [An exposure assessment] should include not only identification of current exposures but also exposures that may occur in the future if no action is taken at the site... The purpose of this analysis is to provide the decisionmakers with an undemanding of both the current risks and potential future risks if no action is taken. Therefore, as part of this evaluation, a reasonable maximum exposure (RME) scenario should be developed, which reflects the type(s) and extent of exposures that could occur based on the likely or expected use of the site (or surrounding areas) in the future.

Although the RI/FS document was the first document to use the term "reasonable maximum exposure (RME)," guidance for developing an RME scenario was provided later in RAGS.

One of the programs established by EPA was labeled Research to Improve Health Risk Assessments (RIHRA). The program's primary objective was to identify the factors that produced the variability and uncertainty in Superfund exposure assessments. RIHRA published a report entitled Exposure Assessment at Superfund Sites (USEPA, 1989c). The report observed that "most Regional risk assessment personnel are relying almost exclusively on the SPHEM and SEAM for use in preparing CERCLA risk assessments. Deficiencies in the guidance documents were supplemented by the EPA regions with open scientific literature, communications with EPA headquarters, contractors, etc. In addition, the RIHRA report identified supplemental guidance documents prepared by EPA Regions I and

IX. One of the recommendations in RIHRA is that further guidance was needed on procedures to calculate best estimate and upper-bound concentrations.

EPA Regional Guidance

Responsibility for determining and explaining the guidance rationale for the exposure assumptions fell on the various EPA regional administrators. For instance, EPA Region I (Connecticut Maine, Massachusetts, New Hampshire, Rhode Island, Vermont) formed a Risk Assessment Group that released the "Region I Supplemental Manual to Risk Assessment Guidance for the Superfund Program" (USEPA, 1989d). This guidance stated that each selected exposure pathway required the estimation of a range of conditions characterized as the "average case" and "reasonable worst case" scenarios.

- In the average case scenario the exposures would "reasonably occur"; however, Region I recognized that the actual level of upper-bound risk was likely to be higher than the average value reported. The quantification of exposures under this scenario would require combining the arithmetic average values of the detected contaminant concentrations with "reasonably conservative exposure parameters."

- The reasonable worst case scenario was intended to provide an upper-bound of the possible risk posed by a contaminated site. Region I guidance in this scenario directed analysts to combine maximum detected contaminant concentrations in each medium with "reasonably conservative exposure parameters."

As with SPHEM and SEAM. the EPA Region I guidance provided for a reportable range of exposure values, but it also called for a greater imperative to communicate and substantiate exposure assumptions and choice of exposure parameters. While no attempt was made to clarify terms such as "reasonable", Region I guidance provided for a set of default exposure parameters, and recommended more communication with EPA remediation project managers.

Region IX (Arizona, California, Hawaii, Nevada, Commonwealth of the Northern Mariana Islands, Republic of Palau, Federated States of Micronesia, The Republic of the Marshall Islands) developed and published a document entitled Recommended Procedures for Implementation of Superfund Risk Assessment Guidelines (USEPA, 1988b) wherein it recommended that risk estimates be "presented and discussed with language describing the uncertainty." Region IX also required the calculation of risk levels for three potential exposures

- Maximally Exposed Individual (MEI), defined as the "site of highest potential exposure (regardless of whether this site is inhabited)."

- Maximally Impacted Residence (MIR), defined as "habitation site experiencing the highest estimated potential exposure."

- Equivalent Exposure Populations (EEP), defined as "populations experiencing roughly equivalent potential risks. " The risk are expressed at order-of-magnitude levels (e.g., 10^{-4}, 10^{-6}, etc.).

Region IX states that the MEI and the worst-case scenario may be useful for screening purposes, not for justifying remediation or setting cleanup levels. Region IX guidelines did not show how to develop the exposure scenarios.

EPA Headquarters Guidance

The Exposure Factors Handbook (EFH). The EPA's guidelines for estimating exposures, as delineated in SEAM, were expanded and improved in the EFH (USEPA, 1989b). The guidelines were developed to promote consistency among the various exposure assessment activities and to standardize exposure assessment calculations. The handbook demonstrates how to apply standard default factors to specific exposure scenarios when site-specific data are not available, and for each scenario, it provides

- basic equations for estimating exposure;

- recommended default values for each parameter in the exposure equations (the default values are presented as averages [intended to represent typical values], ranges [derived from distributions, where possible, basing the lower end on the 50th percentile and the upper end on the 90-95th percentile], and frequency distributions); and

- justification for each recommended value.

The handbook indicates that the recommended default values should be selected to represent a range of scenarios from typical to reasonable worst case, but it recognizes that "EPA does not have an official position on how to define a reasonable" worst case scenario, ...reasonable is a largely subjective term." EFH recommends using the best scientific judgment when combining lower and upper values to "reduce the possibility of creating an 'overly worst case'." Calculating an "absolute worst case" would be useful, however, for the purpose of demonstrating that site risk levels were of no concern.

Risk Assessment Guidance for Superfund. Volume I (RAGS). RAGS (USEPA, 1989a) provides guidance on using the "reasonable maximum exposure" (RME) conceptual framework RAGS defines RME as the "highest exposure that could reasonably be expected to occur for a given exposure pathway." RAGS specifically states that the selection of exposure factors in CERCLA exposure assessments should result in "an estimate of the reasonable maximum exposure." RAGS also indicates that "a determination of "reasonable" cannot be based solely on quantitative information, but also requires the use of professional judgment."

4.2.4 Further Concerns with Superfund Exposure Assessment Guideline Conceptual Framework

Creation of an EPA Risk Assessment Intra-Agency Group in March of 1990

An EPA intra-agency group was formed in March of 1990 "to address concerns regarding inconsistencies among exposure assumptions in Superfund risk assessments" and released an interim final document entitled Supplemental Guidance to RAGS: Standard Default Exposure Factors (USEPA, 199la). According to the EPA intra-agency group, the principal reasons for the inconsistencies were as follows:

- factors derived from site-specific data,
- professional judgment when choosing values for key variables, and
- assumptions based on limited data.

The document provides further guidance on which default exposure factors to use when site-specific data are unavailable. The standard set of default values follows the 1990 NCP directive for quantification of exposures under RME scenarios. This supplemental guidance argues that "further guidance is needed on how to calculate a reasonable maximum exposure, because the RME methodology "has been subject to a variety of interpretations."

Creation of EPA Superfund 30-Day Task Force

A 30-Day Task Force, created as part of a program to improve the effectiveness of the Superfund program, published the report Accelerating Superfund Cleanups and Evaluating Risk at Superfund Sites (USEPA, 199 lb). Continuing concerns raised about the Superfund program's exposure assumptions resulted in a Task Force recommendation for the review of the Superfund risk assessment guidance and policies. The Task Force indicated the need for the exposure assumptions to be reviewed by EPA's Office of Research and Development the Risk Assessment Council, and the Science Advisory Board, as well as by industry and environmental groups. Review of the Superfund risk assessment guidance and policies has resulted to date in the following publications Guidance for Risk Assessment (USEPA, 199lc); Supplemental Guidance to RAGS: Calculating the Concentration Term (USEPA, 1992b); Guidelines for Exposure Assessment (USEPA, 1992a); and An SAB Report: Superfund Site Health Risk Assessment Guidelines (USEPA, 1993).

4.2.5 Addressing Exposure Assessment Guideline Conceptual Framework Concerns

Guidance for Risk Assessment

This document (USEPA, 1991c) was released as part of a memorandum from EPA Deputy Administrator Henry Habicht. The document directs EPA risk assessments to include the central tendency and the high-end portions of the risk distribution when describing individual risk. "High end" was defined as a risk level "conceptually above the 90th percentile of the actual (measured or estimated) distribution, but not higher than the individual in the population who has the highest risk." The high-end scenario was to be perceived as an estimation of the exposure level in an actual population, not a bounding estimate to be perceived as an estimation of the exposure level in an actual population, not a bounding estimate or worst-case scenario. Guidance for Risk Assessment defines bounding estimates of risk as "purposely overestimating the exposure level in order to develop a statement like 'not greater than...'." The "worst-case" scenario was defined as a "combination of conditions producing the highest conceivable risk" This guidance recommends that when complete distributions are not available (most cases) the high-end exposure can be estimated by the following:

- Monte Carlo simulation of distributions if there is sufficient information about the variability of factors, or

- by using maximum, or near maximum, values for some variables, and leaving others at their mean values if there is limited information on the distribution of the exposure.

The document did not indicate which variables should be at their maximum or average values. The choice of the actual values was left to the discretion of the risk assessor.

Supplemental Guidance to RAGS: Calculating the Concentration Term

This supplemental guidance (USEPA, 1992b) was designed to help explain how the concentration term in the RME equation is calculated. It defines RME as the "highest exposure that could reasonably be expected to occur for a given exposure pathway." The concentration term is the result of the calculation of the 95% upper confidence limit (UCL) on the arithmetic average (mean). The 95% UCL is used as an alternative to the maximum detected contaminant value; however, if the sample population size is small (less than 10) the UCL calculation results in a value greater than the maximum detected contaminant concentration. Usually more samples are recommended. If that is not possible, the concentration term defaults to the maximum detected value.

Guidelines for Exposure Assessment

These guidelines, published in response to recommendations from EPA's SAB and the general public (USEPA, 1992a), superseded and replaced the Guidelines for Estimating Exposures (USEPA, 1986b) and Proposed Guidelines for Exposure-Related Measurements (USEPA, 1988d). The guidelines convey the principles of exposure assessments and constitute the current theoretical principles to be used in the Superfund program. The central theme of the document is to move "toward a more realistic approach to exposure determination." Explanations of the following terms are included in the document:

- High-end risk: Risks above the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest risk.

- Maximum Exposed Individual (MEI): The individual with the highest exposure in a given population.

- Maximum Exposure Range: This refers to the uppermost portion of the exposure distribution; this range falls above the 98th percentile of the distribution, but not higher than the individual with the highest exposure (MEI).

- Theoretical upper bounding estimate (TUBE): TUBE was designed to estimate exposure, dose, and risk levels that are expected to exceed the levels experienced by all individuals in the actual distribution. TUBE is calculated by assuming limits for all the factors used to calculate exposure that will provide the highest possible levels of risk (highest concentration, lowest body weight, etc.).

- Worst case: This term refers to the maximum possible exposure, dose, or risk conceivable.

The guidelines mentioned that, historically, the MEI and the reasonable worst case scenario have been equated with the worst case or bounding estimate.

An SAB Report: Superfund Site Health Risk Assessment Guidelines

This SAB report was published as a result of an SAB meeting on April 7-8, 1992, in Bethesda, Maryland. The meeting was organized to review key issues related to RAGS. One of these issues was the definition and calculation of the RME. The SAB supports the RME conceptual framework as a better alternative to the use of the MEI scenario previously used. SAB also agrees with EPA on the reasonableness of using the arithmetic mean, as opposed to the geometric mean, for calculating the concentration term in the exposure equations. However, the SAB is recommending Monte Carlo techniques (i.e., probabilistic approach) as an alternative to the UCL estimate on the mean (i.e., develop frequency distributions for each of the variables needed to calculate exposures).

The SAB report of February 1993 indicates that calculating an RME based on the UCL presents conceptual and practical difficulties. The report maintains that the UCL on the arithmetic average concentration at a site may not be equated with a reasonable maximum exposure. The UCL approach works under the assumption that the site is well characterized, and that samples taken are representative of the possible exposures likely to occur. But because of the spatial distribution of contamination (i.e., existence of hot spots) as it relates to the frequency of exposures, assessors may question the reasonableness of the RME scenario. Also, it is difficult to interpret the exposure value after combining the 95% UCL on the arithmetic average concentration at a site with the 50th and 90th percentile for some of the default values. The SAB report of February 1993 recommends that in the absence of further guidance regarding the quantification of exposures at Superfund sites, some type of "most reasonable" estimate of exposure also be calculated along with the RME.

4.3 Issues and Regulator Dialogue

4.3.1 Average and Upper-End Risk Issues

Review of the documents mentioned in the preceding section indicates that the conceptualization of exposure scenarios has required the use of terms that due to their subjective nature, have been employed under different interpretations. The use of subjective terms to communicate levels of risk to human health from CERCLA sites, and the uncertainty inherent in the estimation of those levels of risk have necessitated the development of supporting guidelines. Specifically, the concept and use of the term RME to frame an exposure scenario indicative of an individual high-end exposure evolved from earlier CERCLA exposure assessment descriptors (i.e., upper bound, MEI, worst case, etc).

Below is a brief summary of how these terms were first used. Section 2 of this chapter describes these documents and the evolution of these terms in more detail.

- SPHEM (USEPA, 1986a): Environmental fate models should use "reasonable worst case" assumptions. Exposure points should use the geographic point of "highest individual exposure." Exposure assessments should estimate a range of exposure scenarios using an "upper-bound and a "best estimate" scenario.

- SEAM (USEPA, 1988a): The uncertainty associated with the estimated level of risk should include a "standard deviation" or the "95% confidence limit"

- Region IX Guidance (USEPA, 1988b): This guidance required the calculation of risk levels for three potential exposures, "maximally exposed individual", "maximally impacted residence," and "equivalent exposure populations."

- RI/FS (USEPA, 1988c): "Reasonable maximum exposure" was introduced, but guidance on its use did not come until RAGS was published in 1989.

- RAGS (USEPA, 1989a): This was the first document to give specific guidance on the use of the term "reasonable maximum exposure". RME was defined as the "highest exposure that could reasonably be expected to occur for a given exposure pathway."

- Exposure Factors Handbook (USEPA, 1989b): Default values are presented as "averages," "ranges" and "distributions. " An "absolute worst case" calculation would be useful for demonstrating that the site risk levels were of no concern.

- Region I Guidance (USEPA, 1989d): Each selected exposure pathway required the estimation of a range of conditions characterized as "avenge case" and "reasonable worst case." The reasonable worst case scenario was intended to provide an "upper bound of the possible risk.

- NCP (USEPA, 1990): The goal of the RME concept is to combine "upper-bound" and "mid-range" exposure factors so that the resulting exposure scenario is "protective and reasonable, not the worst possible case."

- Guidance for Risk Assessment (USEPA, 199lc): Directs EPA risk assessments to include the "central tendency" and the "high end portions of the risk distribution. The "worst-case" scenario was defined as a "combination of conditions producing the highest conceivable risk"

- Guidelines for Exposure Assessment (USEPA, 1992a): Six terms were defined in this document: "high-end risk," "maximum exposed individual", "maximum exposure range," "reasonable worst case," "theoretical upper bounding estimate," and "worst case." High-end risk is defined as being above the 90th percentile of the population distribution, but not higher than the individual with the highest risk MEI is defined as the individual with the highest exposure in a given population. Maximum exposure range is defined as being above the 98th percentile of the population distribution, but not higher than the individual with the highest risk. Reasonable worst case is defined as covering the 90th to 98th percentile of the distribution. TUBE is designed to estimate exposure, dose, and risk levels that are expected to exceed levels experienced by all individuals in the actual distribution. Worst case refers to the maximum possible exposure, dose, or risk that can conceivably occur, whether or not it actually occurs.

- Supplemental Guidance to RAGS: Calculating the Concentration Term (USEPA, 1992b): Calculating the RME should utilize the "95% upper confidence limit" on the "arithmetic average."

- Superfund Site Health Risk Assessment Guidelines (USEPA, 1993): The "upper confidence limit" on the "arithmetic average" concentration at a site may not be equated with a "reasonable maximum exposure. " The document recommends that some type of "most reasonable" estimate of exposure also be calculated along with the RME.

The following issues have been identified relating to the conceptual use of the term RME:

Concept of Reasonableness

Although the concept of "reasonableness" was first introduced as a framework to provide more realistic descriptions of risk estimates, it has resulted in conflicting views among various societal groups. The National Resources Defense Council and the Environmental Defense Fund have declared in the popular press that assumptions contained in Supplemental Guidance to RAGS: Standard Default Exposure Factors result in "abandoning the reasonable worst-case scenario" and provides "less protection to the public" (BNA, 1991). However, the Chemical Manufacturers Association indicated that a "30-year exposure duration is a more reasonable assumption than 70 years," and views the guidance as a "step in the right direction, moving toward a more realistic worst-case assumption" (BNA, 1991). The EPA rationale for the new default values to be used when site-specific information is lacking was designed "to facilitate more consistent evaluation of the risks posed by the Superfund sites," and the, guidance "attempts to reduce unwarranted variability" (USEPA, 199la).

Use of Professional Judgement

Associated with the thematic evolution of the RME, and underlying the quantification of exposures, is the use of professional scientific judgement. Indeed, in the absence of site-specific information (e.g., contaminant characterization, exposed population data, etc.), the best choice for the description of the actual exposure and risk outcome is determined by a *combination of factors chosen by the risk assessor.* The improvement of basic research in the various science branches and its application in the environmental field will inevitably lead to the reduction of uncertain y in risk estimates.

4.3.2 Regulator Dialogue

The need at EPA for greater consistency and comparability among various sites has led to the development and evolution of guidance documents that provide agency-wide standard default factors and procedures to be used in the absence of site-specific factors. RME constitutes the current conceptual framework for how exposure assessments are performed under CERCLA risk assessments.

The current RME definition and applicable policies are found in Guidelines for Exposure Assessment (USEPA, 1992a). The "Supplemental Guidance to RAGS: Calculation of the Concentration Term" (USEPA, 1992a). The "Supplemental Guidance to RAGS: Standard Default Exposure Factors" (USEPA, 1991a) may also provide a better understanding of practical issues in the RME. The first document shows how the concentration term in the RME equation is calculated using the 95% UCL on the mean, explains the significance of the RME, and discusses the basic concepts concerning the concentration term. USEPA (1992b) provides the standard default exposure factors to be used in the Superfund program. The exposure factors in this guidance are considered the most appropriate and are intended to be used under the RME scenario.

The representation of risks posed by contaminants in CERCLA sites will continue to evolve to better represent the scientific, as well as the regulatory, consensus. Whether the EPA accepts the representation of risk as a range of exposure value estimates (Habitch's memo) or as a single value (RME) will be determined by what information the risk manager provides to EPA. The exposure guidelines call for an increased effort to communicate the uncertainty associated with the calculation of risk levels. In discussing the role of exposure characterization, the guidelines state that "risk managers should be given some sense of how exposure is distributed over the population and how variability in population activities influences this distribution" (USEPA, 1992b). The SAB report of February 1993 also recommends that in the absence of further guidance regarding the quantification of exposures at Superfund sites, some type of "most reasonable" estimate of exposure can also be calculated along with the RME.

There have been recommendations for CERCLA risk assessments to consider the use of frequency distributions for the various exposure parameters (probabilistic approach) as an alternative to the use of choosing a single exposure point value for the exposure parameters (deterministic approach). Various key guidance documents, including SPHEM, RAGS, SEAM, and EFH indicated that the probabilistic concept could be a potential alternative; however, EPA has not yet published formal exposure assessment guidance reflecting those recommendations.

Even though EPA has not issued guidance on how to use probabilistic approaches in risk assessments, this does not prevent DOE from using this approach and presenting the results along with the results from the RME scenario. If the probabilistic approach can be shown to be “reasonable,” then these results should be presented as a viable alternative to the RME approach. The uncertainties involved with the probabilistic approach should be clearly discussed in the uncertainties section of the BRA. The negotiation tactics discussed in Section 3.3.2 of this document also apply to the RME scenario presented in this chapter.

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